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Apparat og metode for intubasjonsovervåkning

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Fig. nr 1

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Title:	Intubation monitoring apparatus and method

The present invention relates to an apparatus and a method for assessing correct endo-tracheal intubation immediately after intubation and for monitoring correct placement of the endo-tracheal tube over time.

Endo-tracheal tubes are used during general anaesthesia, intensive care, and cardiopulmonary resuscitation. The endo-tracheal tube is used to secure the airways to the patients lungs. Insertion of an endo-tracheal tube is carried out with the aid of a laryngoscope. This device allows the operator to visually identify the larynx and pass the tube through it into the trachea. In some cases the larynx may not be seen and the chance arises of a tube being erroneously passed into the oesophagus as opposed to the trachea.

An endo-tracheal tube erroneously passed into the oesophagus does not provide an adequate airway, so that the patient may become deprived of oxygen, and serious harm or even death may result.

During transportation or moving of a patient the endo-tracheal tube may be unwantedly relocated, without any clinical signs of this condition appearing before it is too late.

Recognition of correct endotracheal intubation as soon as possible is thus of paramount importance. It is also important to be able to monitor intubation in the cases where there is a risk of unwonted relocation of the tube.

The usual method of confirming the correct location of the tube involves pumping a quantity of air or gas through the tube into the patient. With a stethoscope it is possible to hear normal ventilation sounds if the tube is placed in the trachea. However, in a stress situation and/or a noisy environment, it is difficult to hear these important ventilation sounds.

As a consequence of this, several devices which are not based on hearing ventilation sounds are introduced. These may e.g. be based on pressure and End tidal CO_2 measurements. End Tidal CO_2 measurements are based on an analysis of the patient's expiration air, if this air contains CO_2, it has been in the patient's lungs and the intubation is correct. However, a measurement of CO_2 contents depends on several parameters (blood flow through the lungs, gas exchange in the lungs, ventilation volume per ventilation, ventilation amount per minute, etc). In cases where the blood flow through the lungs is strongly reduced, and the patient ventilation is constant, the End Tidal CO_2 level will be almost cero. This can be wrongly interpreted as an incorrect intubation. As End Tidal CO_2 depends on other physiological parameters for the patient that can be failing at the time intubation is performed, it cannot be considered as a reliable method.

Other devices use the change of transthoracal diameter as a factor to detect correct intubation. Again transthoracic diameter measurement can be affected by several sources of error. Sometimes the patient's thorax is so rigid that it does not expand appreciably by inhalation. In these cases, the abdominal cavity expands as a consequence of diaphragm movement. These will of course be erroneously interpreted as the patient receiving air in the stomach (wrong intubation).

Due to the above mentioned disadvantages related to the prior art methods, there exists a need for an apparatus and a method for assessing correct positioning of an endo-tracheal tube both immediately after intubation and for monitoring its' positioning over time.

The present invention is based on impedance measurement of the thoracic cavity. Impedance measurement involves the use of two electrodes which receive an approximately constant direct (or alternating) current, measurement of the direct (or alternating) voltage between the electrodes and calculation of the ratio voltage/current (impedance).

Cardiac defibrillators perform impedance measurement before applying a power impulse to a patient. The aim of the impedance measurement in this case is to determine the correct power parameters for administration of an electric impulse in resuscitation techniques. Cardiac defibrillators are specially adapted to this function, the electrodes being robust to be able to lead a high voltage pulse many times without being destroyed, the power source being also adapted to provide high power in short periods of time.

The principle behind the invention is that transthoracal impedance of inflated lungs is different from the impedance of deflated (or empty) lungs. This is due to the presence of a longer current path between electrodes when the lungs are inflated. The invention makes use of this change in impedance to distinguish between correct and incorrect intubation. When the endo-tracheal tube is placed in the trachea and the lungs are ventilated, a change in transthoracal impedance will be noticeable immediately. On the contrary, when the tube is placed in the oesophagus or stomach it will not be possible to measure any significant impedance change of the thorax.

The invention comprises thus an apparatus for immediate and continuous position monitoring of an endo-tracheal tube for ventilation of patients. The apparatus comprises:

- at least two measuring electrodes adapted for measurement of thoracic impedance,
- a power source for activating the measuring electrodes,
- a user interface device to start/stop the monitoring,

- a display or an alarm device for signalling whether the lungs are being inflated or not, and consequently whether the intubation device is correctly or incorrectly positioned, and
- a connection unit for transmitting signals between the electrodes, the power source, the user interface device and the display device.

In a preferred embodiment of the invention the connecting unit comprises a processing unit for: receiving a start command from a user interface device, controlling the measurement process, calculating and analysing impedance signals, identifying significant impedance changes over time, and transmitting a signal representative of "ventilation" or "no ventilation" to a display or an alarm device, and a memory unit for storage of measured, calculated and reference values.

The invention comprises also a method for assessing and monitoring placement of an endo-tracheal tube for ventilation of patients, where a) thoracic impedance signals are obtained based on measurement data obtained from measurement electrodes,
and characterised by,
b) analysing the impedance signals to identify changes in impedance over time,
c) comparing the impedance changes to a predetermined threshold value, and
d) activating a display or alarm device if the changes' magnitude exceeds the predetermined value.

In an advantageous embodiment of the method according to the invention, steps a)-c) are performed at a processing unit connected to measurement electrodes, and the threshold value is stored in a storage unit connected to the processing unit. In a further variant of this embodiment, previous to steps a) a start signal is given to the processing unit by a user, and steps a)-d) are repeated a during a predetermined period of time or until a stop signal is given to the processing unit by a user

It is important to point out that the apparatus according to the invention only has a low power consumption, since it only requires power for impedance measuring devices, processing/memory devices and alarm devices. This clearly distinguishes the invention from defibrillator devices, which require high power. Since the power needs of the apparatus according to the invention are low, it is possible in one embodiment, to provide an apparatus where the power source comprises portable batteries.

The measurement electrodes in the apparatus according to the invention are also adapted to low power requirements. They are small and have high sensibility towards current signals.

In a simplified version, the apparatus comprises an activating switch (user interface device), two electrodes and a light emitting device. When the electrodes are in place on the patient's chest, the apparatus is turned on. The patient's impedance is measured and as soon as a change in impedance which exceeds a predetermined threshold is detected the light emitting device is turned on. The light emitting device will be activated as long as the impedance value lies over the threshold and will be turned off automatically when the impedance decreases below it. This embodiment permits a continuous monitoring of the intubation.

It is possible to provide the device with a switch having three positions: off, single measurement, monitoring. In the "off" position impedance, detection is not performed. In the "single measurement" position, the apparatus measures the impedance value a predetermined number of times or during a predetermined period of time before it stops. This operation modus will be useful for monitoring adult patients because once the intubation is correct the chances of the tube coming out of place are low. In the "monitoring" position, the measurements will be performed continuously until the apparatus is turned off. This operation modus is useful for monitoring of small children and also for monitoring patients in turbulent conditions (in a helicopter, a boat, mountain rescue, etc). In the "monitoring" position, it is also possible to measure and analyze the patient's breathing rate, and to activate a further alarm device if this rate does not lie within a predetermined range.

It is also possible to supply the apparatus with several light/sound emitting or display devices. This will help avoid the situation where no alarm is activated due to failure of the equipment. A preferred embodiment of the invention will then have a first signal output indicating that there is ventilation of the lungs and a second signal output indicating absence of ventilation. This second signal output will be activated after a predetermined period of time (e.g. 5 seconds) without an impedance change being detected.

In one embodiment of the invention, the apparatus comprises a device for controlling the batteries' charge condition and a device for checking correct functioning of the alarm devices (light/sound emitting devices). This device comprises in one embodiment a display showing battery charge condition and e.g. a button that upon pressure forces a connection of the light/sound device to the battery so that said device is activated.

The apparatus can also comprise devices for control of the electrodes.

The user interface device can also in one embodiment of the invention permit inputting reference and threshold values for thoracic impedance to the processing

units. It can also permit inputting patient characteristics, as e.g. patient age or choosing between patient groups to specify which group the patient belongs to.

Although the apparatus according to the invention is in one embodiment envisaged as an independent portable apparatus, it is also possible to incorporate it in defibrillators or other devices used in resuscitation/monitoring procedures (e.g. ECG devices).

As soon as the pads or electrodes are placed on the thorax the apparatus will measure the unique impedance for that patient at "resting" level, this value will be stored together with a time reference for later use. It is documented that each thorax has its unique impedance. When the amount of air or blood in the thorax is changed either by ventilation or by blood flow or by chest compressions (in cardiac arrest) the thoracal impedance will change. A new measurement and a comparison with the stored value will result in a significant difference in impedance values if the lungs are inflated. Only one ventilation is then needed to measure impedance change due to an air volume change of the thorax.

The invention will now be explained in further details by means of non limiting examples illustrated in the attached drawings, where:

Figure 1 shows a view of an embodiment of the apparatus according to the invention,

Fig. 1 shows an embodiment of the apparatus according to the invention. The apparatus comprises a housing 1 containing a user interface device 2, which in this case is a revolving switch with "on" and "off" positions. The housing contains also a power source (not shown) in the form of portable batteries, a light emitting device 3 and a sound emitting device 4. Electrodes e1 and e2 are connected to the housing by means of cables 5. In this embodiment of the invention, the light and sound emitting devices (3 and 4 respectively) will be activated if a significant change in thoracic impedance is not detected after a preset time period. It is possible to envisage an embodiment comprising several light/sound emitting devices or a display device that are activated selectively according to the magnitude of the thoracic impedance changes.

The term "impedance" refers generally to a complex value comprising a resistive and an inductive/capacitive part, but it is clearly possible to implement the invention by measuring only the resistive/capacitive and/or inductive part of the impedance. The measurements can be performed by means of AC or DC voltage/current. In the DC case, only the resistive part of the impedance will be measured.

It will be evident that measurement of voltage/current/conductance may be employed in an equivalent way for determining the thoracic impedance.

Fig. 2 shows how the apparatus 1 according to the invention will cooperate with an endotracheal tube 6. If the tube 6 is positioned correctly, the trachea 7 will transmit a flow of air to the lungs 8, these will inflate and an impedance value will be measured by means of electrodes e1 and e2. If this value represents a significant increase in thoracic impedance, the intubation will be correct and the light/sound emitting devices will not be activated. If said value on the contrary does not represent a significant increase in thoracic impedance, the light/sound emitting devices will be activated.

Fig. 3A shows a diagram of thoracic impedance vs. time for a breathing patient. From the diagram it is clear that the respiratory activity causes considerable changes in transthoracic impedance.The respiratory impedance will have a variation of 0,5 Ω between peak and valley (figure 3B).

Fig. 4 shows a block diagram of an embodiment of the apparatus according to the invention. The figure shows measuring electrodes e1 and e2 adapted for measurement of thoracic impedance, a power source 9 for activating the measuring electrodes e1 and e2, a user interface device 2 to start/stop the monitoring, a processing unit 10 for: receiving a start command from user interface device 2, controlling the measurement process, calculating and analysing impedance signals, identifying significant impedance changes over time, and transmitting a signal representative of "ventilation" or "no ventilation" to the display or an alarm device 3, 4, a memory unit 11 for storage of measured, calculated and reference values.

Fig. 5 shows a diagram representing one embodiment of the method according to the invention. In step 20 a start command is transmitted from the user interface device 2 to the processing unit 10. In step 21 an impedance (Z1) measurement is performed by means of electrodes e1 and e2 and processing unit 10. In order to establish a change in impedance value, a reference value (Z0) must be supplied to the processing unit 10. Availability of the reference value Z0 is controlled (Z0 can be at the storage or memory unit 11 or can be inputted by means of the user interface device 2) in step 22. If Z0 is available, an impedance change (Zch) is calculated by means of the processing unit 10 in step 23 and this change is compared with a threshold value (Zthr) in step 24. The threshold value Zthr must also be available in the storage or memory unit 11, or provided by means of the user interface device 2. If the threshold value is not reached (step 25) a "no ventilation" condition will be assessed and the corresponding alarm units 3, 4 will be activated by means of the processing unit 2. In this embodiment of the invention the

measurement/comparison/alarm activating process will continue as long as a stop signal is not given by the user interface device 2. If the apparatus is turned off (step 28) the process will end. If the threshold value is reached or exceeded (step 26) a "ventilation" condition will be confirmed and the corresponding alarm units will be activated.

If a reference value Z0 is not available, the result of the first measurement or a magnitude derivated from earlier measurements will constitute a new Z0 (step 29), and the process will continue as stated before in relation to steps 21 to 28.

The memory or storage unit 11 further comprises a memory portion contaning executable computer program instructions for performing the method according to the invention when executed by the processing unit 10.

The implementation of these executable instructions is an ordinary task for a person skilled in the art, based on the disclosure of the invention.

Figure 5 shows one possible embodiment of the method, but other variants are also possible. The reference value Z0 and the threshold value Zthr can be stored in a table according to the patient's characteristics (sex, age, weigth, etc.). The user interface device can have a further switch to chose between patient groups and thus establish the current Z0 and Zthr values.

The output signal of the apparatus according to the invention (light/sound/image) for monitoring intubation will not be influenced by ambient noise (as opposed to the prior art stethoscope technique, it being difficult to hear lung sounds with a stethoscope), low cardiac output (which will influence ET CO_2 measurements), and does not imply the delay of several ventilation attempts before satisfied.

The apparatus can be used for monitoring adults, children, and newborns. As stated before, it may be used as an alarm device during intensive care and transportation of all age groups of patients, in order to monitor correct placement of the tube.

The invention comprises also a method for immediate detection of correct/incorrect intubation, that is instant detection of correct/incorrect placement of the tube during intensive care and transportation of intubated patients.

CLAIMS

1. Apparatus for assessing and monitoring placement of an endo-tracheal tube for ventilation of patients, comprising:
- at least two measuring electrodes adapted for measurement of thoracic impedance,
- a power source for activating the measuring electrodes,
- a user interface device to start/stop the monitoring,
- a display or an alarm device for signalling whether the lungs are being inflated or not, and consequently whether the intubation device is correctly or incorrectly positioned, and
- a connection unit for transmitting signals between the electrodes, the power source, the user interface device and the display device.

2. Apparatus according to claim 1,
characterized in that the connection unit comprises
- a processing unit adapted for: receiving a start command from a user interface device, controlling the measurement process, calculating and analysing impedance signals, identifying significant impedance changes over time, and transmitting a signal representative of "ventilation" or "no ventilation" to a display or an alarm device,
and that the device further comprises
- a memory unit for storage of measured, calculated and reference values.

3. Apparatus according to claim 1,
characterized in that the power source consists of portable batteries.

4. Apparatus according to claim 1,
characterized in that the user interface device comprises an "on/off" switch or a three position switch, a first "off" position, a second "single measurement" position, and a third "monitoring" position.

5. Apparatus according to claim 1,
characterized in that the alarm device comprises a sound emitting device and/or a light emitting device.

6. Apparatus according to claim 1,
characterized in that the processing unit is adapted for calculating and analysing impedance in deflated and inflated lungs, for storing measured impedance

values in the storage unit, and for creating reference values based on measured values when no reference values are present in the storage unit.

7. Apparatus according to claim 1,
c h a r a c t e r i z e d i n that the user interface is adapted for inputting reference thoracic impedance values, threshold impedance values, and/or patient characteristics to the processing unit.

8. Apparatus according to any of the preceding claims,
c h a r a c t e r i z e d i n that it is adapted for integration in a defibrillating device.

9. Use of an apparatus for measurement of thoracic impedance for controlling and monitoring endotracheal intubation.

10. Method for assessing and monitoring placement of an endo-tracheal tube for ventilation of patients, where a) thoracic impedance signals are obtained based on measurement data obtained from measurement electrodes,
c h a r a c t e r i z e d i n that it further comprises
b) analysing the impedance signals to identify changes in impedance over time,
c) comparing the impedance changes to a predetermined threshold value, and
d) activating a display or alarm device if the changes' magnitude exceeds the predetermined value.

11. Method according to claim 10,
c h a r a c t e r i z e d i n that steps a)-c) are performed at a processing unit connected to measurement electrodes, and that the threshold value is stored in a storage unit connected to the processing unit.

12. Method according to claim 11,
c h a r a c t e r i z e d i n that previous to steps a) a start signal is given to the processing unit by a user and that steps a)-d) are repeated a during a predetermined period of time or until a stop signal is given to the processing unit by a user.

13. Computer program stored in a memory, for execution by a processing unit,
c h a r a c t e r i z e d i n that it comprises instructions which on execution perform a method according to one of the claims 10-12.

ABSTRACT

The invention comprises an apparatus and a method for assessing and monitoring placement of an endo-tracheal tube for ventilation of patients based on thoracic impedance measurement.

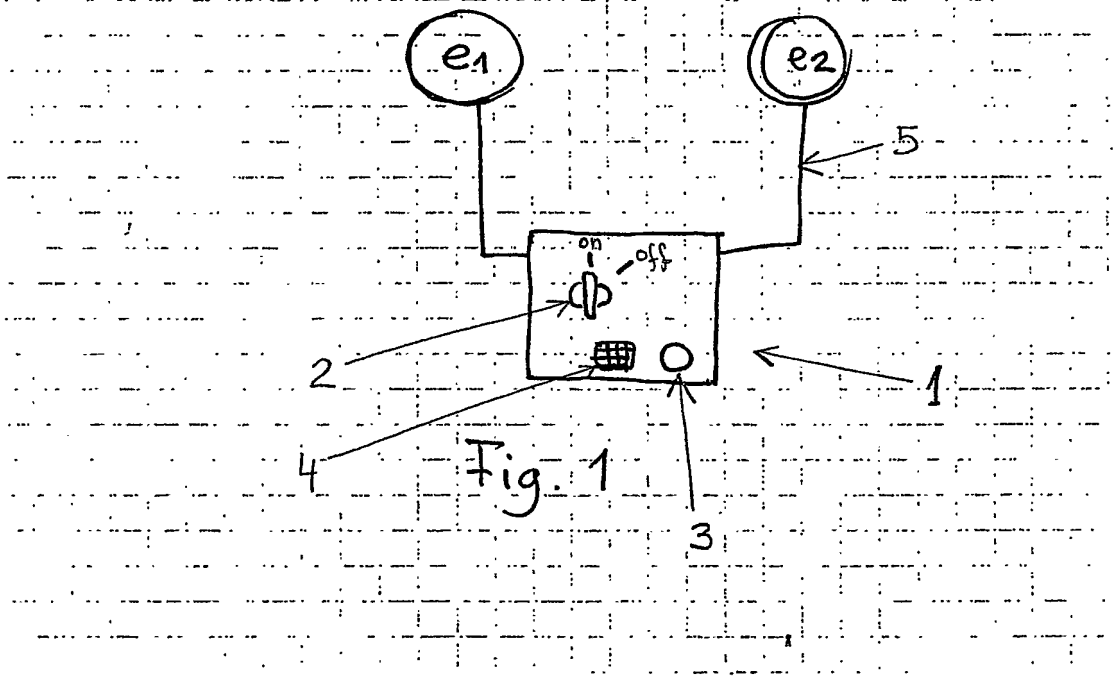


Fig. 1

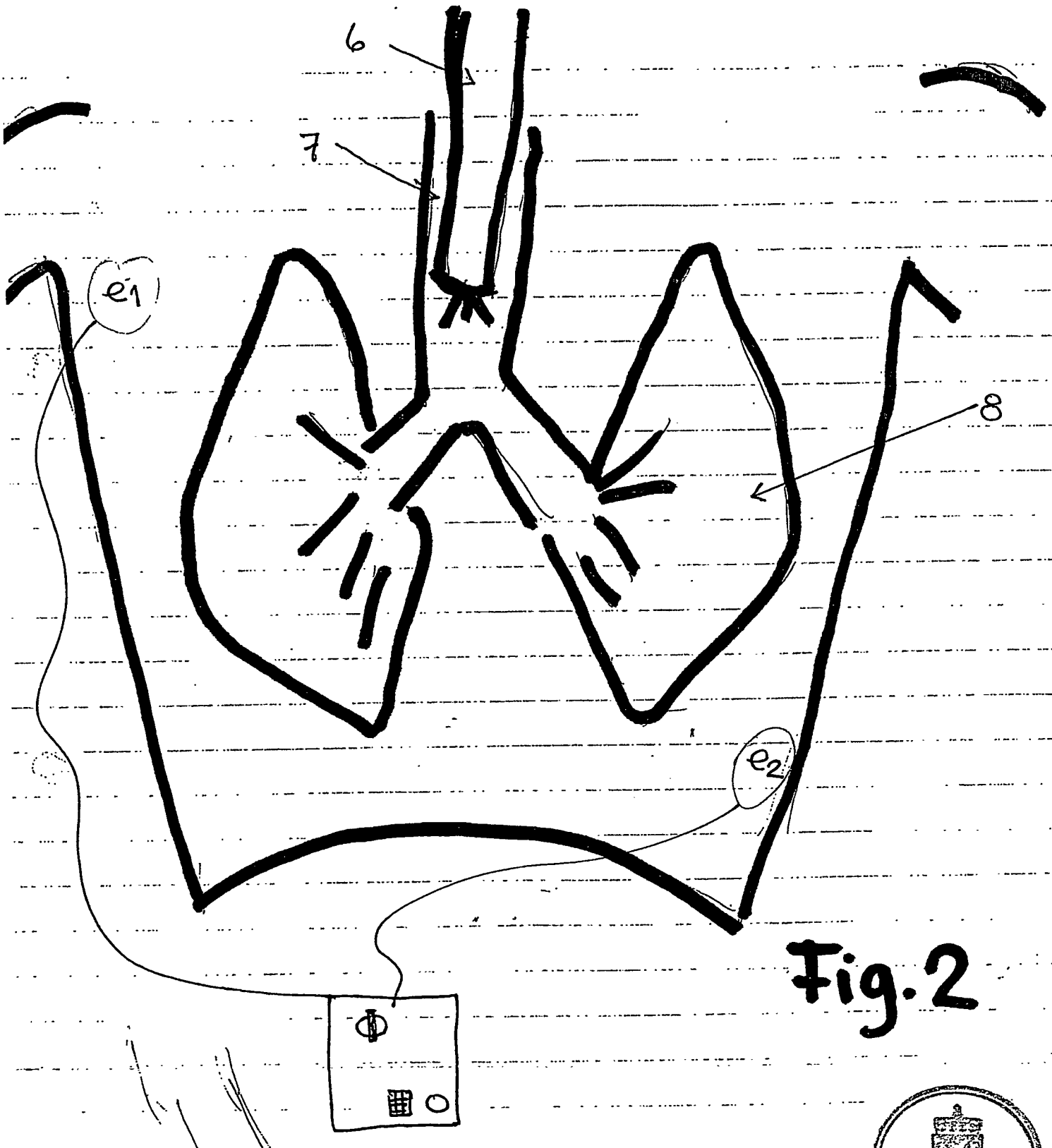


Fig. 2

Figure 3A

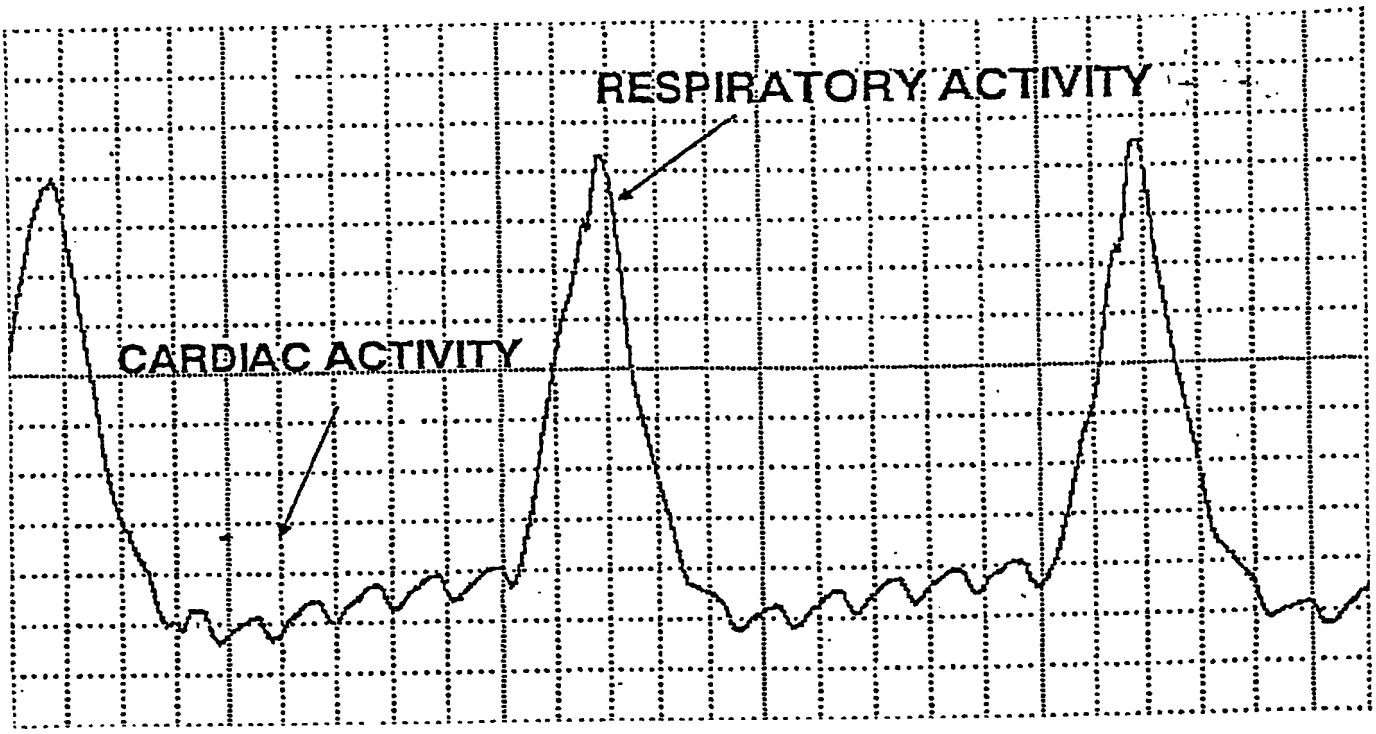
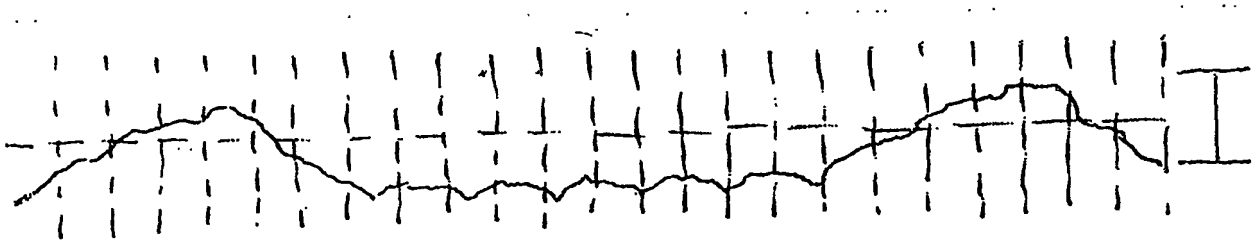


Figure 3B



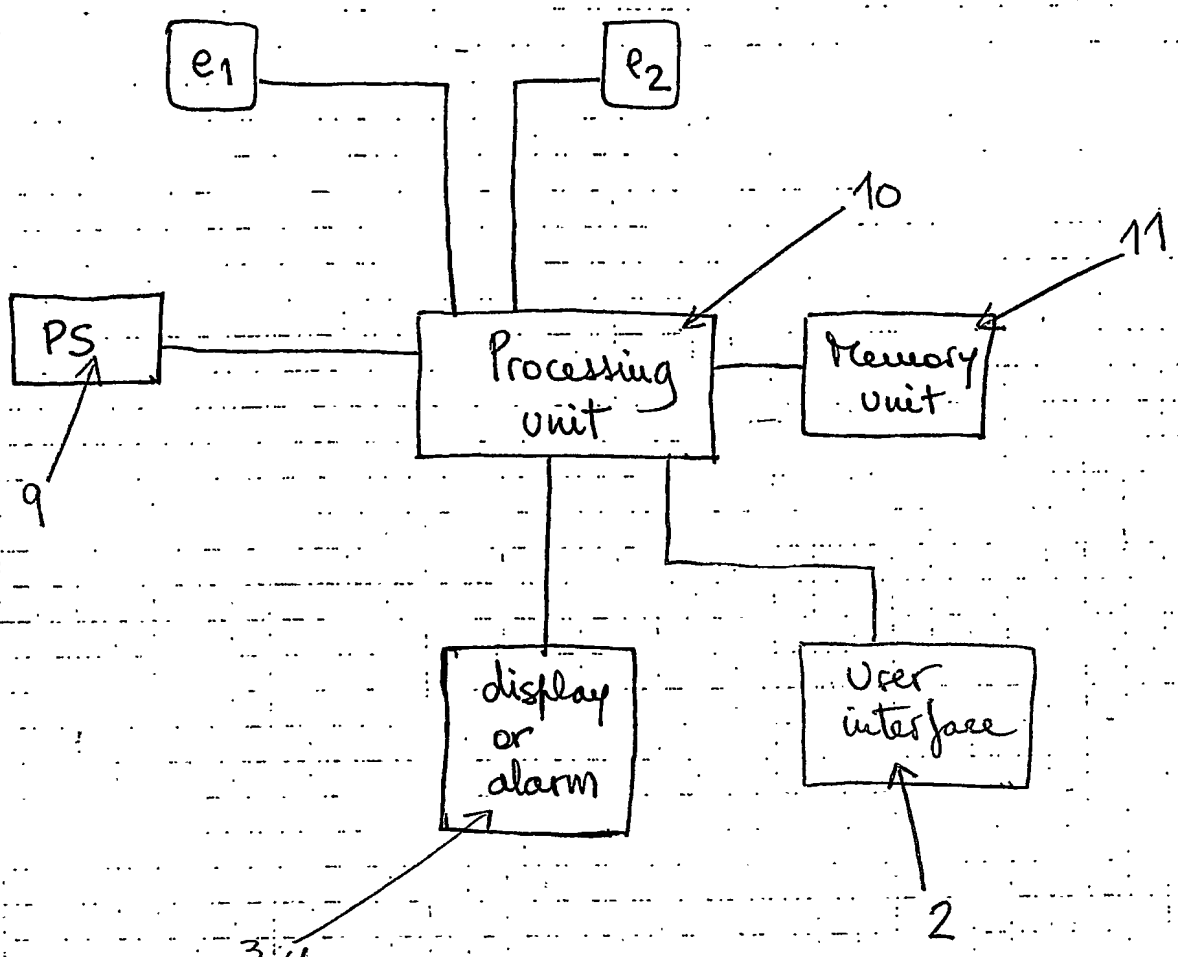
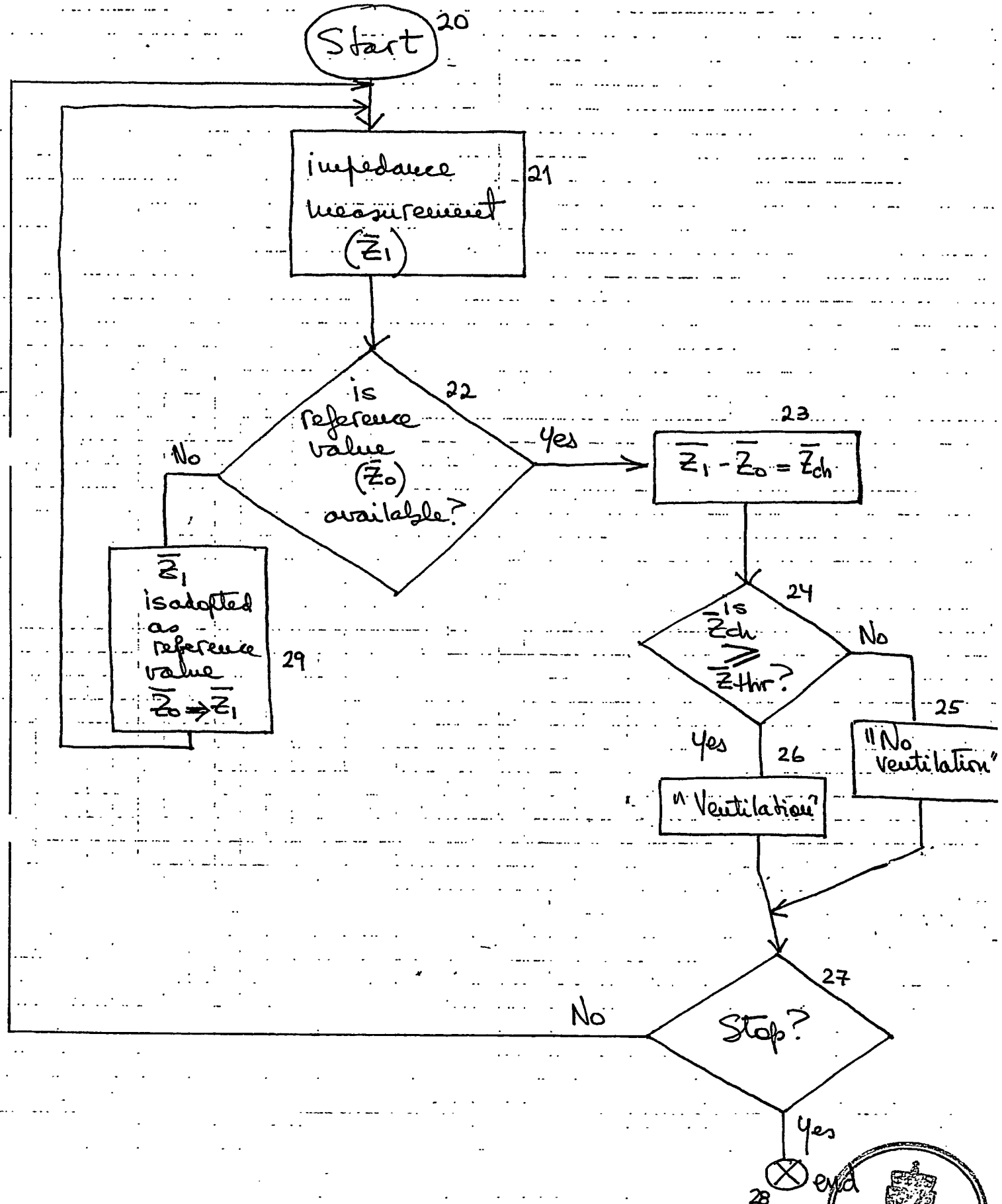


Figure 4



Figur